REMARKS

Claims 21 through 49 were pending in the application. By this amendment, claims 21 and 43 have been amended. Reconsideration and withdrawal of the rejections is requested in view of the foregoing changes to the claims and the following remarks.

The following remarks are intended to address all of the grounds for rejecting the claims set forth in the pending Office Action.

I. Double Patenting

Claims 21, 25, 28, 32, 33, and 43 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32, 35, and 36 of copending Application Serial No. 10/734,547. In view of the provisional nature of the rejection, and without acceding to the Examiner's contention of commonality of claimed subject matter between the two applications, Applicant will respond to this rejection at such time that it is asserted non-provisionally.

II. Claim Rejections under 35 U.S.C. § 103(a)

Claims 21-25, 36, 37, and 40-47 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sonnenschein et al. (US 2001/0056282) in view of El Gazayerli (USP 6,159,146). In addition, claims 26-35, 48, and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sonnenschein and El Gazayerli, in further view of Kalloo et al. (US 2002/0022851). Finally, claims 38 and 39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sonnenschein and El Gazayerli, in further view of Reed (US 2003/0165887). Without acceding to the grounds for rejecting the claims, Applicant responds as follows.

To establish a prima facie case of obviousness under 35 U.S.C. § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. Obviousness can only be established by combining or modifying the teachings of the

prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103(a) is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

Claim 21 recites a method for performing a medical procedure that includes, *inter alia*, the steps of advancing an overtube within a hollow body organ in a flexible state, transitioning the overtube to a rigid state, advancing a plication device through the overtube, and forming a tissue fold within the hollow body organ with the plication device. By the present amendment, claim 21 has been amended to recite that the plication device is advanced through the overtube "after the overtube has been transitioned to the rigid state." Support for this amendment is provided throughout the specification, such as, for example, at paragraphs 0255-0257 and FIGS. 40B-C.

The Sonnenschein method, on the other hand, does not include the recited step of advancing a plication device "after the overtube has been transitioned to the rigid state." The Office Action (at page 3) identifies the Sonnenschein stapling assembly 61, 61A as corresponding with the recited plication device, and states that "the plication device is advance through the overtube in the manufacturing process since when the overtube is placed into the stomach it already contains the plication device." As a result, Sonnenschein does not – and by its very description cannot – describe or teach the recited method step.

The El Gazayerli patent and the Kalloo and Reed publications do not correct the deficiencies of the Sonnenschein publication. None of these references describes a method that includes the step of advancing a plication device through an overtube after the overtube has been transitioned to a rigid state.

Accordingly, because at least these elements recited in claim 21 are not disclosed, taught, or suggested by the Sonnenschein publication, or by the combination of Sonnenschein with any of the other cited references, there can be no prima facie case of obviousness of claim 21. The claim, and all of its dependent claims (i.e., claims 22-42), should be allowed.

Turning to claim 43, that claim recites a method for performing a medical procedure that includes, *inter alia*, the steps of advancing a main body having a plication device within a hollow body organ in a flexible state, transitioning the main body to a rigid state, and forming a tissue fold within the hollow body organ with the plication device. By the present amendment, claim 43 has been amended to recite that the plication device comprises "a tissue grabbing assembly and a flexible tube containing one or more tissue anchors." Support for this amendment is provided throughout the specification, such as, for example, at paragraphs 0082-86 and 0249, and at FIGS. 1-3, 40, and 41.

The Sonnenschein method, on the other hand, does not include the recited step of advancing a main body having a plication device "comprising a tissue grabbing assembly and a flexible tube containing one or more tissue anchors." The Office Action (at page 6) identifies the Sonnenschein stapling assembly 61, 61A as corresponding with the recited plication device. There is nothing in the Sonnenschein publication, however, that describes or suggests using a tissue grabbing assembly and a flexible tube containing one or more tissue anchors as a substitute for the disclosed stapling assembly. As a result, Sonnenschein does not describe or teach the recited method step.

The El Gazayerli patent and the Kalloo and Reed publications do not correct the deficiencies of the Sonnenschein publication. None of these references describes a method that includes the recited step of advancing a main body having a plication device comprising a tissue grabbing assembly and a flexible tube containing one or more tissue anchors.

Accordingly, because at least these elements recited in claim 43 are not disclosed, taught, or suggested by the Sonnenschein publication, or by the combination of Sonnenschein with any of the other cited references, there can be no prima facie case of obviousness of claim 43. The claim, and all of its dependent claims (i.e., claims 44-49), should be allowed.

Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented,

but rather as an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ02512**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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